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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,985	02/26/2004	Chuang Chun Chiueh	CHIU3034/EM	2667

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/785,985	CHIUEH, CHUANG CHUN	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9,11-17 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,9,11-17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and response filed November 1, 2005 is acknowledged and entered. Claims 1-4, 9, 11-17 and 19 remain pending and under examination.

2. The objection to claims 1-4, 16, 17 and 19 for the reciting improper Markush group language is overcome by Applicant's amendment.

The rejection of claims 3, 4, 6-11 and 14-18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is moot in view of the cancelled claims and withdrawn in view of Applicant's amendments to the claims.

The rejection of claims 1-19 under 35 U.S.C. 103(a) as being unpatentable over Hirahashi and Gemma, is moot in view of the cancelled claims, and modified with regard to claims 1-4, 9, 11-17 and 19. The rejection has been modified to include an additional reference, see below.

Claim Rejections - 35 USC § 112

3. The rejection of claims 1-4, 9, 11-17 and 19 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims as amended are drawn to agents against that prevent viral infection comprising compositions containing assigned amounts of C-phycocyanin, allophycocyanin and

Spirulina growth factor. Previously, the claims were drawn to prophylactic agents against viral infection. The terms prophylactic and preventative are synonymous, encompassing the prevention of viral infection in this context. Applicant's amendment of the claims to recite, "prevents viral infection", does not change the scope of the claims such that the rejection is overcome.

Applicant has not demonstrated the preventative effects of any or all of C-phycocyanin and/or allophycocyanin and/or Spirulina growth factor. In order for prevention to be demonstrated, suitable animal models must be challenged with the appropriate pathogen after having been previously treated with C-phycocyanin and/or allophycocyanin and/or Spirulina growth factor. Applicant has not shown experiments or literature that supports the instant claims to prevention of viral infections. One of skill in the art would not expect C-phycocyanin and/or allophycocyanin and/or Spirulina growth factor to completely prevent viral infection of any virus without having seen proof that it works in at least an acceptable animal model of disease. Therefore, the claims as written are not enabled for their intended use as a preventative measure against viral infection.

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily drawn to the following:

Applicant points to the specification, page 2, line 17 through page 3, line 20. The specification discloses that phycocyanin is capable of inhibiting enterovirus and influenza virus. Applicant also points to US Patent 6,346,408, disclosing allophycocyanin as an anti-viral substance that inhibits enterovirus reproduction as a well as influenza virus reproduction.

In response to Applicant's arguments, the Office acknowledges that phycocyanin and allophycocyanin are capable of inhibiting several viruses. However, the claims are not limited to virus inhibition, rather, prevention of viral infection. In order for the instant claims to be enabled, the prevention of virus entry with phycocyanin or allophycocyanin must be demonstrated or known. The prior art literature and Applicant's specification disclose the ability of phycocyanin and allophycocyanin to reduce or inhibit virus production. Prevention of viral infection is evidenced by challenge experiments in acceptable animal models. Applicant has failed to provide such data or point to similar data in the prior art literature of record. Therefore, the rejection is maintained. Suggested language is, "An oral anti-viral agent, comprising...".

Claim Rejections - 35 USC § 102

4. The rejection of claims 1, 2, 14 and 16 under 35 U.S.C. 102(b) as being anticipated by Hirahashi *et al.* (*International Immunopharmacology*, 2002, 2 :423-434, "Hirahashi"). Note that the claims are rejected only for recited elements, not their intended use as a preventative agent of viral infection. The claims as amended are drawn to an oral agent against viral infection comprising 3%-45% C-phycocyanin, 1%-15% allophycocyanin, and 96%-40% Spirulina growth factor. C-phycocyanin, allophycocyanin and Spirulina growth factor are in a water-soluble formula, such as a powder or granule.

Hirahashi discloses that Spirulina, which naturally contains C-phycocyanin, allophycocyanin and Spirulina growth factor, has anti-viral effects in humans (abstract and page 423, second column, last sentence). In a study that Hirahashi conducted, 12 healthy male volunteers were administered 50 mL of Spirulina extract orally every day. The soluble extract

was prepared from a spray-dried powder of *S. platensis* (page 424, second column). The instant claim limitations are met by the teachings of Hirahashi and are therefore anticipated.

Applicant's arguments have been carefully considered, but fail to persuade. Applicant argues that the concentrations of C-phycocyanin, allophycocyanin and Spirulina growth factor are specifically claimed in percentages. Hirahashi is silent on the specific percentages of C-phycocyanin, allophycocyanin and Spirulina growth factor in Spirulina.

In response to Applicant's argument, the specific percentages of C-phycocyanin, allophycocyanin and Spirulina growth factor in the claims are actually broad. The claimed composition comprises anywhere from three to 45% C-phycocyanin, from one to 15% allophycocyanin, and 96 to 40% Spirulina growth factor. In some embodiments, Spirulina growth factor is 96% of the composition, with trace amounts of C-phycocyanin and allophycocyanin. Hirahashi is silent on the percentages of C-phycocyanin, allophycocyanin and Spirulina growth factor in Spirulina, however, given the broad range and variability of the claimed components, one would entirely expect Hirahashi's Spirulina preparation to contain 3%-45% C-phycocyanin, 1%-15% allophycocyanin, and 96%-40% Spirulina growth factor.

5. Claims 1, 2, 14, 16 and 19 remain rejected under 35 U.S.C. 102(a) as being anticipated by Gemma *et al.* (*The Journal of Neuroscience*, July 2002, 22(14):6114-5120, "Gemma"). Note that the claims are rejected only for recited elements, not their intended use as a preventative agent of viral infection. The claims as amended are drawn to an oral agent against viral infection comprising 3%-45% C-phycocyanin, 1%-15% allophycocyanin, and 96%-40% Spirulina growth

factor. C-phycocyanin, allophycocyanin and Spirulina growth factor are in an enteric-coated formula.

Gemma discloses the administration of Spirulina supplement (0.33% w/w dry Spirulina) to rats by blending the regular diet and Spirulina into a dry powder and then administering by oral gavage with 0.5 mL of water, or in rat chow (page 6115, first column, "Materials and Methods" section). By nature, Spirulina contains C-phycocyanin, allophycocyanin and Spirulina growth factor.

Applicant's arguments have been carefully considered, but fail to persuade. Applicant argues that the concentrations of C-phycocyanin, allophycocyanin and Spirulina growth factor are specifically claimed in percentages. Gemma is silent on the specific percentages of C-phycocyanin, allophycocyanin and Spirulina growth factor in the Spirulina supplement.

In response to Applicant's argument, the specific percentages of C-phycocyanin, allophycocyanin and Spirulina growth factor in the claims are actually broad. The claimed composition comprises anywhere from three to 45% C-phycocyanin, from one to 15% allophycocyanin, and 96 to 40% Spirulina growth factor. In some embodiments, Spirulina growth factor is 96% of the composition, with trace amounts of C-phycocyanin and allophycocyanin. Hirahashi is silent on the percentages of C-phycocyanin, allophycocyanin and Spirulina growth factor in Spirulina, however, given the broad range and variability of the claimed components, one would entirely expect Gemma's Spirulina preparation to contain 3%-45% C-phycocyanin, 1%-15% allophycocyanin, and 96%-40% Spirulina growth factor.

6. Claims 1-4, 9, 11-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirahashi or Gemma in view of Hayashi *et al.* (US 5,585,365, "Hayashi"). The claims are drawn to an oral agent comprising water-soluble or enteric-coated formulae. Various formulae are claimed with ratios of compounds and ranges of concentrations. The enteric coating is comprised of 10-30% water-soluble formula, 15% solid additive and 75%-55% vegetable oil.

The teachings of Harahashi and Gemma are summarized above. Both teach Spirulina compounds that naturally contain C-phycocyanin, allophycocyanin and Spirulina growth factor. Neither teaches enteric coatings or combinations of water-soluble and enteric-coated formulae.

However, Hayashi teaches Spirulina extracts formulated into tablets, among other formulations for consumption (abstract) as an anti-viral agent. It would have been obvious to formulate Harahashi and Gemma's compositions into tablets. One would have been motivated by Hayashi's multiple formulations for Spirulina as a therapeutic agent. Formulating the compositions of Spirulina from Harahashi and Gemma into a tablet is conducive for ease of administration (no needles), time (swallowing pills) and cost (no needles, no administrator). One would have had a reasonable expectation of success that Spirulina extracts would be successfully integrated into a tablets because Hayashi formulates Spirulina extracts into tablets.

With regard to combining the water-soluble and the enteric-coated forms of the claimed composition, it would have been obvious to combine the two forms together into one composition. The common function of Spirulina taught by Gemma and Hayashi is anti-viral, not to mention the fact that both products are themselves Spirulina. So the identity and the functions are the same. Therefore, one would have been motivated to combine the known products because the products are the same in content and function. Given that the products are the same

in structure and function, one would have had a reasonable expectation of success that combining the two products would have worked together to combat viral infection.

With regard to the various concentrations of the compounds claimed, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. It would have been obvious and well within the skill of the ordinary artisan to optimize the concentrations of Spirulina and its components. Unless there is evidence indicating such concentrations discovered by Applicant are critical to the invention, they do not render the claims patentable over Hirahashi and Gemma. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been carefully considered, but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

- Applicant argues that none of the cited references of the Office action of August 1, 2005, teaches an enteric-coated formulation of C-phycocyanin, allophycocyanin and Spirulina growth factor.
    - In response to this argument, the rejection has now been modified to include a reference that teaches Spirulina extracts in tablet form (see reasoning above).
- Applicant argues that the compositions of Gemma and Hirahashi are not used for the same purpose. Gemma discloses improved beta-adrenergic receptor function, down-regulation of proinflamatory cytokines and decreased MDA in the cerebellum, and is ultimately concerned with combating aging in rats. Hirahashi administers a hot water

extract of Spirulina in order to activate the innate immune system and ultimately suppress cancer development and viral infection. These uses are not the same.

- In response to Applicant's argument, the new rejection set forth above addresses this issue. Gemma and Hayashi disclose one common function of their Spirulina compositions: anti-viral applications.

❖ Applicant argues that neither of Gemma and Hirahashi discloses specific concentration ranges. Without this knowledge (the specific concentrations), one of ordinary skill in the art would not know how to optimize the concentration of components that are not expressly disclosed in the prior art references. Applicant also argues that the ratio of water-soluble formula to enteric-coated formula recited in the present claims and the ratio of the total amount of C-phycocyanin and allophycocyanin to Spirulina growth factor are novel and unobvious.

- In response to this argument, the specific concentrations of C-phycocyanin and allophycocyanin to Spirulina growth factor are admittedly absent from Hirahashi, Gemma and Hayashi. However, as stated above, some of the concentrations of C-phycocyanin and allophycocyanin to Spirulina growth factor are so broad as to be encompassed by the concentrations that are naturally present in the hot water extracts of Hirahashi, Gemma and Hayashi. With regard to the specific concentrations and ratios of compounds to compounds, the patentability of the claims does not rely on these numbers, lacking evidence to the contrary. It would have been well within the skill of the ordinary artisan to adjust the ratios of the two compositions to desired concentrations. Therefore, the invention as a whole

would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

7. No claim is allowed. Because the Office action presents new/modified rejections, this action is non-final. The Office regrets any inconvenience to Applicant.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
January 17, 2006